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Amendment No. 1 to SB1197

Crowe
Signature of Sponsor

AMEND Senate Bill No. 1197* House Bill No. 1190

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 63-10-204, is amended by adding the following as new subdivisions to be appropriately designated:

( ) “Authentication” means to affirmatively verify, only when a pedigree is required pursuant to Tennessee Code Title 63, Chapter 10, Part 2, before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

( ) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(A) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(B) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis;

( ) "Pharmacy warehouse" means a permanent physical location for prescription drugs that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to pharmacies that have the same common ownership or control. Pharmacy warehouses must be licensed as wholesale distributors;

( ) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer;

( ) “Drop shipment” means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer’s co-licensed product partner, that manufacturer’s third party logistics provider, or that manufacturer’s exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy warehouse, pharmacy or other person authorized by law to dispense or administer such drug, and the pharmacy warehouse, pharmacy or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer’s co-licensed product partner, or that manufacturer’s third party logistics provider, or that manufacturer’s exclusive distributor or from an authorized distributor or record that purchased the product directly from the manufacturer or one of these entities.

( ) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug;

(B) Is licensed as a wholesale distributor under this chapter; and

(C) To be considered part of the normal distribution channel, must also be an authorized distributor of record;

( ) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, or by drop shipment from a manufacturer of the prescription drug, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(A) An authorized distributor of record, to a pharmacy to a patient, patient’s agent or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(B) An authorized distributor of record, to a pharmacy warehouse to that pharmacy warehouse's intracompany pharmacy to a patient, patient’s agent, or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(C) A pharmacy warehouse to that pharmacy warehouse's intracompany pharmacy to a patient, patient’s agent or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(D) A pharmacy to a patient or patient’s agent;

(E) Other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(F) An Authorized Distributor of Record to one other Authorized Distributor of Record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient.

(G) Another entity as prescribed by the board's regulations;

( ) "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug, excluding all devices and veterinary prescription drugs, which leaves the normal distribution channel. The pedigree shall minimally include the following information for each transaction:

(A) The source of the prescription drug, including the name and principal address of the seller;

(B) The proprietary and established name of the prescription drug, the amount of the prescription drug, the national drug code number, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(C) The business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;

(D) Information that states that the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased;

(E) A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury; and

(F) Other items as prescribed by the board's regulations;

( ) "Third party logistics provider" means an entity that:

(A) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition;

(B) Is licensed as a wholesale distributor under this chapter; and

(C) To be considered part of the normal distribution channel must also be an authorized distributor of record;

( ) "Wholesale distribution" means the distribution of prescription drugs or by wholesale distributors to persons other than consumers or patients, and

includes the transfer of prescription drugs by a pharmacy to another pharmacy if the total number of units transferred during a twelve (12) month period exceeds five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period. Wholesale distribution does not include:

(A) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription;

(B) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons, as defined by the FDA.

(C) Intracompany transactions, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control, or any transaction or transfer between co-licensees of a co-licensed product;

(D) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals, pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(E) The sale, purchase, or trade of a prescription drug, or the offer to sell, purchase, or trade a prescription drug by a charitable organization described in 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(F) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization

or from other hospitals or similar health care entities that are members of these organizations;

(G) The transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

(H) The sale, purchase, or trade of blood and blood components intended for transfusion;

(I) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, health care clinic, physician's offices, pharmacy, pharmacy warehouse, or charitable institution in accordance with the board's regulations for return to the original manufacturer , originating wholesale distributor, or to a third party returns processor; or

(J) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's regulations.

(K) The distribution to a licensed prescriber of drug samples by manufacturers' and authorized distributors' representatives where the samples are intended for use of the prescriber’s patients and not for re-sale;

(L) The sale of minimal quantities of prescription drugs by pharmacies to licensed prescribers for office use;

(M) Distribution of drugs that are earmarked by state, federal or local government for use in emergencies or disasters, or for use in declared state, federal or local government emergencies or disasters;

(N) Distribution of drugs to under title 63, chapter 10, part 5;

(O) The distribution of drugs by a repackager that is licensed with the FDA as a repackager;

(P) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(Q) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer , originating wholesale distributor, or to a third party returns processor.

(R) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier’s usual course of business, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug.

( ) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into the state, including but not limited to manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, colicensees, exclusive distributors, third party logistics providers, pharmacy warehouses that conduct wholesale distribution, wholesale drug warehouses, independent wholesale drug traders, and pharmacies that conduct wholesale distributions.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:

(a)

(1) Effective January 1, 2008, wholesale distributors shall be required to maintain a pedigree for each prescription drug that is wholesale distributed outside the normal distribution channel, in accordance with policy and procedure set by the board. This subdivision (a)(1) will expire when a date is set under subdivision (a)(2).

(2) The board of pharmacy shall determine a targeted implementation date for electronic track and trace technology. Such a determination shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in the State of Tennessee. After consultation with interested stakeholders and prior to implementation of the electronic track and trace technology, the board shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the recommended electronic track and trace technology will be no sooner than July 1, 2010, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

(3) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, or a pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or a pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of this section, so long as they are exempt

from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance. Both licensees under this section and pharmacies shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product

(b)

(1) Each wholesale distributor that provides services in this state, whether the wholesale distributor is located within this state or outside of this state, shall be licensed by the board and shall renew the license using an application provided by the board.

(2) The board shall promulgate rules to establish standards and requirements for the issuance and maintenance of a wholesale distributor license.

(3) The board shall have the authority to recognize a third party to inspect or accredit wholesale distributors.

(A) The board shall develop and implement an approval process for third party inspectors/accrediting organizations with the feedback from an advisory group consisting of representatives of the distributors, manufacturers, pharmacies and other stakeholders. Such criteria and standards shall include guidelines and training processes for third party/accreditation inspectors, and safeguards for protecting the confidentiality of proprietary information obtained during the inspection/accreditation process.

(B) Individual third party personnel/inspectors must demonstrate to the board that they have received training and/or demonstrate familiarity with the inspection standards. Evidence such as a letter of certification from a training program, notice from the inspector’s employing third party organization, or other means

recognized by the board shall be accepted as meeting the requirement.

(4) The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state, if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) The applicant is inspected or accredited by a third party recognized and approved by the board. An applicant that is accredited by a third party recognized and approved by the board, shall not be subject to duplicative requirements set by the board. If an applicant inspected, but not accredited by a third party, that applicant must comply with the licensing requirements set by the board through regulation.

(5) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three (3) years.

(c) Manufacturers engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in FDA regulations 21 CFR Part 205 to provide wholesale distribution services.

(d)

(1) If a person negligently or recklessly engages in the wholesale distribution of prescription drugs in violation of this section, the person has committed a Class C felony.

(2) If a person knowingly and willingly engages in wholesale distribution of prescription drugs in violation of this section, the person

has committed a Class C felony, and in addition to imprisonment may be fined not more than fifty thousand dollars ($50,000).

SECTION 3. This act shall take effect January 1, 2008, the public welfare requiring it.